

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number: 10/662,594

Filing Date: 09/15/2003

Applicant: Arnold

Application Title: Use of androst-4-ene-3, 6, 17-trione...

Examiner: Spivack

571-273-0585

Faxed and mailed April 29, 2005

Assistant Commissioner of Patents

Washington, D.C. 20231

RESPONSE / AMENDMENT

In response to the Office Action dated 12/01/04, Applicant submits the following amendment:

1. Applicant has submitted the reference requested by the examiner.
2. Rejection of the claims under 35 USC 112, first paragraph, is seen as inappropriate because of the enabling nature of the example provided. The example is for a relatively small group that illustrates the useful and effective nature of the invention. The specification is not limited to that example, however the study illustrates the effectiveness for a representative group. The findings of that study are presented as showing the results for those subjects. The benefits of the invention are presented for increasing the testosterone levels in all males. While the study did not measure the quantitative amount of testosterone level increases for males outside the group,

the manner of production of testosterone in the male body indicates that so long as the male was capable of producing testosterone, administration of the compound according to the invention would yield greater testosterone levels.

3. There are no distinctions made in the benefits of the invention for young adult males versus aging males. There may be benefits to users in both categories. Young males who may be interested in bodybuilding or increasing testosterone levels for health or reproductive reasons have utilized the invention. Older males, finding a natural drop-off of testosterone, sometimes called “andropause” have been able to restore testosterone levels using the invention.

4. Products made using the invention are being sold by the assignee as 6-OXO brand nutritional supplements under the ERGO PHARM brand. These products have achieved commercial success and have been found to be effective for adult males of any age. Other products on the market have caused increases in estrogen levels, causing a feminization effect, sometimes reflected in the development of enlarged breasts. The present invention has been found by some to be an effective way of limiting those problems. Applicant submits that the product has achieved commercial success and been shown to be effective. The specification is enabling, in that there is no distinction in the study group and all males, as described. Those skilled in the art, as well as those having ordinary skill, are enabled to administer the compound as described in the specification for males of any age. No undue experimentation or In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (“The test of enablement is whether one reasonably

skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

5. Section 2164.04 of the Manual of Patent Examination Procedure describes a rejection based on enablement:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

Applicant requests an explanation of why the Examiner indicates that the specification is not clear on the administration of the compound, and why the example of a particular age range of males is insufficient to show enablement for administration of the compound in all males.

7. Please delete claim 6.

8. Please add new claims 7 and 8 as follows:

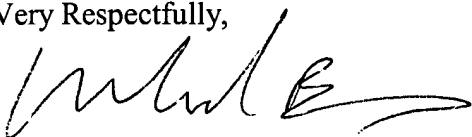
7. (New) The method of increasing endogenous testosterone production in men according to claim 1, wherein the man is between the ages of 18 and 80.

8. (New) The method of increasing endogenous testosterone production in men according to claim 1, wherein the man is between the ages of 32 and 40.

9. Applicant presents the specification and claims as being patentable. Applicant's Attorney would welcome discussing this application and amendment with the Examiner and if the application is found to be insufficient in any way, requests assistance of the Examiner in placing the application in condition for allowance.

I certify that I have transmitted this paper by facsimile and Express Mail to the Patent and Trademark Office on April 29, 2005.

Very Respectfully,

A handwritten signature in black ink, appearing to read 'Michael Berns', with a stylized flourish at the end.

Michael Berns

USPTO Attorney 38,379